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LAWS OF NATURE VERSUS MAN MADE
CREATIONS: A BALANCING APPROACH TO
PATENT ELIGIBILITY IN ASSOCIATION FOR
MOLECULAR PATHOLOGY V.
MYRIAD GENETICS, INC.

*Salina Tariq**

I. INTRODUCTION

In the face of the growing concerns of patent eligibility in the fields of science, the Supreme Court has continually attempted to make the law as clear as possible. But given the evolutionary nature of scientific understanding, the Court is not in the best position to, nor is capable of, introducing a bright line rule that will encompass all future scientific discoveries. The nature of scientific study is such that an “invention” in that field cannot possibly be free of any reliance upon the laws of nature. Yet, the Supreme Court in its decisions has consistently adhered to the laws of nature exception to patent eligibility.¹ While it is widely understood that “laws of nature” is essentially a term of art,² with no specific definition, the Court has managed to formulate a general understanding that the exception does not apply when the product seeking patent protection has certain distinct characteristics from the naturally-occurring product that it derives from.³ This definition has somewhat eased the difficulty faced by scientific innovators in negating the exception, given that it is inevitable that their products will include some natural components. The determination of whether a product falls within this exception requires a case-by-case identification of the discovery or invention at issue. The most important question in any patent eligibility suit then becomes “What type of invention or discovery is it?”⁴

In the case of *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the United States Supreme Court confronted the issue of patent eligibility of a scientific discovery pertaining to the isolation of human DNA se-

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1. *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1290 (2012).
2. Eileen M. Kane, *Patent Ineligibility: Maintaining A Scientific Public Domain*, 80 ST. JOHN'S L. REV. 519, 542 (2006).
3. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).
4. See Kane, *supra* note 2, at 519.

quences.⁵ The Court once again struck down an argument for a broader application of patent protection, holding that an isolation of DNA, albeit possible only after exhaustive experiments to find the DNA's precise location, was not an "invention" for purposes of the patent law.⁶ The Court thereby solidified its existing interpretation that for a discovery to meet the "novel" requirement of patent eligibility, it must involve the undertaking of an additional step that distinguishes the product discovered from the naturally-occurring product that it is derived from.⁷ The Court's understanding was not only consistent with its precedent, but also successful in balancing the twin goals of the Patent Act⁸: encouraging new innovations by providing an economic incentive and promoting such advancements by limiting the application of patent protection. Finding broad patentable subject matter would restrict innovation to the potential accomplishments of a single mind. After all, how is it possible to advance in the fields of science while simultaneously restricting the use of scientific knowledge and tools? Doing both, as one critic illustrated, would be like allowing a single company to patent a generic invention "car," causing all drivers to buy the car manufactured by that company, only for it to turn out to be the unsafe Pinto.⁹

II. FACTUAL BACKGROUND

Certain medical patients, advocacy groups, and doctors brought an action against Myriad Genetics, Inc. ("Myriad"), a research laboratory, seeking a declaration that Myriad's patents for isolating DNA in genes and creating composite DNA ("cDNA") were invalid.¹⁰

Myriad's chief scientist discovered the precise location and sequence of two types of genes: BRCA1 and BRCA2.¹¹ The mutation of these genes has been known to dramatically increase the risk of breast and ovarian cancer.¹² This knowledge of the location enabled Myriad to isolate the genes and develop certain medical tests for detecting mutations in a patient's BRAC1 and BRAC2 genes.¹³ The tests were to be used to determine a patient's cancer

5. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2109 (2013).

6. *Id.* at 2117.

7. *See id.* (quoting *Chakrabarty*, 477 U.S. at 309).

8. 35 U.S.C. § 101.

9. Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 90 (2002).

10. *Myriad Genetics*, 133 S. Ct. at 2114.

11. *Id.* at 2112.

12. *Id.*

13. *Id.*

risk.¹⁴ Following the discovery, Myriad obtained patents for isolating BRCA1 and BRCA2 genes and the synthetically created molecules of cDNA.¹⁵ The patents were obtained so that Myriad would have the exclusive right to isolate the DNA, which is necessary to obtain the genetic information of the BRCA genes, and the exclusive right to synthetically create BRCA cDNA.¹⁶

Isolation of genes is necessary for genetic testing.¹⁷ Other laboratories, including the University of Pennsylvania's Genetic Diagnostic Laboratories ("GDL"), offered BRCA testing once knowledge of such isolated sequences became known.¹⁸ Petitioner Dr. Harry Ostrer ("Ostrer"), a researcher at New York University, often sent his patients' DNA samples to GDL for testing.¹⁹ When Myriad learned of this, it sent letters to GDL and Ostrer, informing them of its patents and alleging that the genetic testing was an infringement of those patents.²⁰ The letters offered collaboration licenses that permitted very limited BRAC related testing. GDL responded by agreeing to cease such testing and informed Ostrer of its decision.²¹ Myriad continued to assert its patent rights against others by filing infringement suits that led to settlements whereby defendants agreed to stop conducting BRCA testing.²²

III. DESCRIPTION OF PLAINTIFFS' CLAIM

The Association of Molecular Pathology, along with certain medical patients, advocacy groups, and doctors, initially filed the suit in the District Court of the Southern District of New York, seeking declaratory relief on the grounds that Myriad's patents did not cover patentable subject matter consistent with the Patent Act, and were thereby invalid.²³ Plaintiffs argued: (1) DNA sequences occur naturally and are therefore exempt from patent protection; (2) Myriad neither created nor altered the naturally occurring genetic information of the genes, or the genetic structure of the DNA.²⁴ The patents-

14. *Id.*

15. *Id.*

16. *Myriad Genetics*, 133 S. Ct. at 2113.

17. *Id.* at 2114.

18. *Id.*

19. *Id.*

20. *Id.*

21. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1315 (Fed. Cir. 2012) *cert. granted in part*, 133 S. Ct. 694 (2012) *and aff'd in part, rev'd in part sub nom. Myriad Genetics*, 133 S. Ct. at 2120 (2013).

22. *Id.*

23. *Id.* at 1309.

24. *Id.* at 1326.

in-suit included isolated DNA containing all or part of the BRCA1 and BRCA2, and methods used to assess the gene sequences to identify genetic mutations associated with cancer risks.²⁵

IV. PROCEDURAL AND SUBSTANTIVE HISTORY

The District Court of the Southern District of New York held that Myriad's patents for isolated DNA sequences, as well as the methods used to conduct the genetic testing, were both invalid because neither the methods nor the isolation of DNA changed the composition of the naturally-existing products in a manner that made the isolated DNA "markedly different."²⁶

On July 29, 2010, the United States Court of Appeals for the Federal Circuit affirmed in part and reversed in part, holding that the DNA sequences were patentable because by isolating the sequences, Myriad changed the molecular composition of what existed naturally.²⁷ Similarly, the Federal Circuit held that the method claim of screening cancer patients via changes in cell growth rates was a patentable method, even though it involved a basic scientific principle, because the method involved an additional transformative step.²⁸ Finally, the court held that the method claim involving comparing and analyzing BRCA sequences was not patentable because it involved only abstract mental processes.²⁹

On March 26, 2012, the United States Supreme Court granted a petition for writ of certiorari and vacated the judgment in light of the decision in *Mayo Collaborated Services v. Prometheus Laboratory, Inc.*³⁰ However, on remand August 16, 2012, the Federal Circuit again came to its prior conclusion.³¹

On November 30, 2012, the United States Supreme Court again granted the petition for writ of certiorari,³² and a decision was made on June 13, 2013.³³

V. SUPREME COURT HOLDING AND OVERVIEW OF RATIONALE

The Court unanimously held: (1) A naturally occurring DNA segment was a product of nature and not entitled to patent eligibility merely because it

25. *Id.* at 1309–10.

26. *See id.* at 1330.

27. *Ass'n for Molecular Pathology*, 689 F.3d at 1331.

28. *Id.* at 1336.

29. *Id.* at 1334.

30. *Id.* at 1308.

31. *Id.* at 1309.

32. *Myriad Genetics*, 133 S. Ct. at 2116.

33. *Id.* at 2120.

was isolated;³⁴ and (2) cDNA was synthetically created in a laboratory and was patent eligible because formulating it included the additional step of removing certain unwanted naturally-occurring codes, as is required in order to sever and isolate.³⁵ The rationale was that the isolated DNA sequence of BRCA1 and BRCA2 genes exist in that same genetic location and order in the human body with or without the isolation.³⁶ Although isolating the segment was a groundbreaking discovery, the usefulness of the discovery was not a factor in determining patent eligibility.³⁷ In order to claim patent rights, Myriad needed to have conducted at least one additional step to ensure that the product it claimed to have created was an act of invention rather than a mere discovery.³⁸

VI. COURT'S RATIONALE

The Court began its analysis by reiterating its long-standing decision that the Patent Act implicitly excludes laws of nature, natural phenomena, and abstract ideas from patent eligibility; such subject matters are basic tools of scientific and technological work.³⁹ The exception was created to ensure that broad grants of patents covering such basic tools would not inhibit innovation, thereby directly conflicting with the very purpose of patent law.⁴⁰ Products of nature, in that case, should be equally available to everyone.⁴¹ The Court relied on its previous decision in *Diamond v. Chakrabarty*, which held that a product of nature is only patentable if its characteristics are markedly different from what is found in nature.⁴²

Myriad contended that the isolated DNA was not a product of nature because the extensive process of isolation rendered the segment different from the non-isolated segment found in nature.⁴³ Myriad's argument rested on the presumption that all compositions of matter were ultimately derived from nature, therefore a rule requiring a distinct composition from what naturally existed would make patents impossible to obtain.⁴⁴

In response, petitioners argued that products of nature were exempt from patent protection, regardless of whether the product had been changed

34. *Id.* at 2117.

35. *Id.* at 2119.

36. *Id.* at 2116.

37. *Id.* at 2117.

38. *Myriad Genetics*, 133 S. Ct. at 2117.

39. *Id.* at 2116 (quoting *Mayo*, 132 S. Ct. at 1293).

40. *Chakrabarty*, 447 U.S. at 309.

41. *Id.*

42. *See id.*

43. *Ass'n for Molecular Pathology*, 689 F.3d at 1325.

44. *Id.*

from its natural form, unless the change is one that alters the product's name, character, or use thereby making it markedly distinct from its natural character.⁴⁵ This argument relies on the presumption that isolation did not alter the genetic composition of the DNA segment enough to justify completely banning anyone's use of that genetic composition.⁴⁶

The United States Patent and Trademark Office ("PTO") took the position that man-made DNA molecules (such as cDNA) created by removing certain codes are patent eligible; whereas mere isolations of DNA segments, without anything more, are not.⁴⁷

The Court ultimately deferred to its precedent: no matter how incredible and advantageous a discovery, that particular fact alone does not satisfy the Patent Act requirement.⁴⁸ Myriad's discovery of the gene sequence location was groundbreaking information in the field of medical science.⁴⁹ However, the patents obtained in light of this discovery simply described the extensively repetitive process of narrowing down possible locations of the genes, not the creation of a new process.⁵⁰ The information that BRCA genes could be used to assess cancer risk was known before Myriad discovered the location.⁵¹ The Court acknowledged that the process of discovering the location required comprehensive effort; but effort, like usefulness, was not sufficient to satisfy the Patent Act.⁵²

The Court held that even though isolating the genes involved breaking chemical bonds, the claims that Myriad patented did not rely on the chemical changes caused by breaking the bonds.⁵³ Myriad's claims involved the information found in the BRCA1 and BRCA2 genes.⁵⁴ Had Myriad only patented the unique segment of the two genes that it had isolated, others could still have used the information in the genes by breaking the chemical bonds in a way that resulted in DNA sequences including only BRCA1 gene or BRCA2 gene, or both genes with other additional genes.⁵⁵ Such isolations would again give others the information found in those genes.⁵⁶ Therefore, obtaining a patent to keep others from isolating genes in the particular sequence

45. *Id.* at 1326; *see Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887).

46. *Ass'n for Molecular Pathology*, 689 F.3d at 1326.

47. *Id.* at 1349-50.

48. *See Myriad Genetics*, 133 S. Ct. at 2117; *see also* 35 U.S.C § 101.

49. *Myriad Genetics*, 133 S. Ct. at 2117.

50. *Id.* at 2118.

51. *Id.* at 2110.

52. *Id.*

53. *Id.*

54. *Id.* at 2118.

55. *Myriad Genetics*, 133 S. Ct. at 2118.

56. *Id.*

of the molecule it discovered would not award Myriad a monopoly in the BRCA genetic information.⁵⁷ Thus, even though the Court upheld the patentability of the actual cDNA molecule pieced together by Myriad, the genetic information found in that molecule was not patentable.⁵⁸

The Court also rejected Myriad's argument that the PTO's past practice of patenting genes should be given deference.⁵⁹ The Court came to this conclusion by distinguishing the past patentable plant genes from the genetic information in dispute.⁶⁰ The plant genes were patentable under the Patent Act due to certain other statutes that provided such patent protection to certain plant breeds.⁶¹ Congress subsequently endorsed the special protection in an amendment of the Patent Act.⁶² There had been no such Congressional endorsement in the context of human genes.⁶³

The Court expressly stated that its holding did not apply to any method claims.⁶⁴ If Myriad discovered the location of BRCA1 and BRCA2 genes by isolating the genes via a method that it had invented, it potentially could have obtained a method patent.⁶⁵ But since the method Myriad employed to isolate the DNA was a widely used scientific method, and any scientists searching for the location would have likely used the same method, that method is not an invention for purposes of patent protection.⁶⁶

VII. CRITIQUE OF COURT'S APPROACH

The human body is full of valuable undiscovered knowledge that could lead to significant medical advancement. Discovery of such knowledge often involves comprehensive understanding of biological complexities and exhaustive medical research. Long hours of labor are typically common in uncovering useful information. However, such hard work and labor may no longer be enough to successfully claim a right in the discovery of that constructive knowledge. Although no discovery could arguably be more useful than one that could potentially save lives, these discoveries are often rewarded with fewer rights than trivial discoveries that require an additional

57. *See id.*

58. *Id.* at 2119.

59. *Id.* at 2118–19 (citing *J.E.M. Ag Supply, Inc., v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2008)).

60. *Id.*

61. *Myriad Genetics*, 133 S. Ct. at 2118 (citing 7 U.S.C. § 2321 and 35 U.S.C. §§ 161–64).

62. *Id.*

63. *Id.* at 2118–19.

64. *Id.*

65. *Id.*

66. *Id.* at 2119–20.

step to be of any use. This is because usefulness and effort are no longer relevant in determining whether a discovery is worthy of patent protection.

The *Myriad* Court was faced with the inevitable dilemma of what level of protection will adequately encourage useful innovation, and at the same time, promote additional inventions based on pre-developed concepts and tools.⁶⁷ These conflicting goals would not be possible without a sufficient balance. If the Court were too cautious in approving patents for experimental processes conducted on naturally-occurring products, it would remove the financial incentive to conduct groundbreaking scientific experiments. On the other hand, being too generous in awarding patent protection to such experimentation could hinder other potential discoveries of equal importance by keeping others from utilizing the fruits of valuable research and experimentation.

In the case of medical science, particularly where human genes with the potential to save lives are involved, the Court has another consideration to keep in mind: When will awarding a monopoly in essential scientific tools and information place too high of a burden on those who have the propensity to benefit most from such valuable innovations? In this case, granting human genome patents would not only hinder scientific innovation, it would also keep patients from easy and cost-effective access to the medical advancement achieved from the study of such genes, thereby detrimentally affecting health care.

After undergoing the foregoing considerations, the Court ultimately followed precedent, and continued to uphold its rationale that certain natural laws and phenomena are exempt from the Patent Act.⁶⁸ The Court seemingly asserts that providing economic incentives by broadly privatizing science and technology do not necessarily have the desired consequences that the law seeks to accomplish.⁶⁹

In *Chakrabarty*, a microbiologist filed patent claims for certain naturally existing bacterium, which had the propensity to break down multiple components of crude oil.⁷⁰ The Supreme Court held that not all living things were exempted from the Patent Act.⁷¹ Instead it found that the bacterium at issue constituted a newly manufactured microorganism because its characteristics markedly differed from the characteristics of bacterium found in nature.⁷² The bacterium in *Chakrabarty*, unlike the human genes in *Myriad*, did undergo an additional process that sufficiently altered its composition.⁷³ The

67. See *Myriad Genetics*, 133 S. Ct. at 2116.

68. *Id.*

69. See *id.*

70. *Chakrabarty*, 447 U.S. at 305.

71. *Id.* at 311.

72. *Id.* at 310.

73. *Id.* at 305.

newly manufactured bacterium was a product of human ingenuity “having a distinctive name, character, and use.”⁷⁴ No naturally occurring bacteria had all the characteristics necessary to break down multitude components of crude oil, unlike the BRCA gene segment that was naturally capable of assessing cancer risks.⁷⁵

In *Mayo*, the patent claims at issue included specific dosage of drugs that were metabolized differently by patients with autoimmune diseases.⁷⁶ The Supreme Court found the patents invalid because the concept of the correlation between concentrations of metabolites in blood and ineffective dosages of thiopurine drugs was common knowledge,⁷⁷ just as the Court found in *Myriad* that the concept that mutations in BRCA genes could help determine propensity to cancer was widely known. Like the defendant in *Myriad* whose experiments comprised of repetitive tests to ascertain the precise location of naturally existing genes, the defendant in *Mayo* merely conducted extensive experiments to determine the correct dosages of a pre-existing drug.⁷⁸

The Supreme Court in *Funk Brothers Seed Co. v. Kalo Inoculant Co.* found that patentee had discovered only “some of the handiwork of nature.”⁷⁹ In this case, it was widely known that bacteria could fix nitrogen, and farmers routinely “inoculated” their crops with bacteria to manipulate nitrogen levels in the soil to improve it.⁸⁰ However, the same bacteria could not be used to achieve the optimum nitrogen levels in all plants.⁸¹ The patentee combined several different bacteria to formulate a single inoculant and obtained a patent.⁸² The Court again held that the combination of bacteria did not alter the bacteria that existed naturally in any way, therefore making the mixture of bacteria ineligible for patent protection.⁸³ Permitting a patent for merely mixing the naturally occurring bacteria, similar to the mere finding of the BRCA location in *Myriad*, would be equivalent to allowing Newton exclusive rights to the laws of gravity.⁸⁴

74. *Id.* at 309–10 (quoting *Hartranft*, 121 U.S. at 615).

75. *See id.* at 305.

76. *Mayo*, 132 S. Ct. at 1290.

77. *Id.* at 1291.

78. *Id.* at 1290–91.

79. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

80. *Id.* at 128–29.

81. *Id.*

82. *Id.* at 130.

83. *See id.* at 132; see also *Mayo*, 132 S. Ct. at 1293 (“A new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter.” Thus, Newton could not have patented the law of gravity.).

84. *See Funk Bros. Seed*, 333 U.S. at 130.

The *Myriad* Court followed precedence and uniformly applied the law to the facts of the case.⁸⁵ The holding, therefore, does not deviate from the already existing law regarding patent eligibility in general, other than providing further clarification of the meaning of “natural law” in connection with human genome sequences.⁸⁶ So even though the decision may not be groundbreaking in the context of exceptions to patent law, the Court once again held that when it comes to choosing between encouraging advantageous natural discoveries and preserving natural tools, the preference will be always be given to the latter without evidence of some concrete creation.⁸⁷ After all, like the Court stated in *Mayo*, neither Einstein, nor Newton could have patented their discovery of natural laws: $E=mc^2$ and gravity.⁸⁸ Had such patents been permitted, any advancement in physics and technology since then would have ceased to exist. Privatizing valuable scientific tools discourages growth in the fields related to the patent. For example a researcher who wants to find a cure for breast cancer would first have undergo extensive negotiations with all the various patent holders who have pecuniary claims to any of the information relevant to the mutations of the gene. There is little doubt that such a time consuming and financially burdensome procedure may effectively influence the researcher in extending his efforts elsewhere. Therefore, in its decision to limit patent law to truly innovative discoveries, the *Myriad* Court reached a sound conclusion supported by judicial precedence.⁸⁹ When a discovery involves a natural phenomenon, it must be accompanied with an additional useful invention to achieve patentable status.⁹⁰

VIII. CONCLUSION

Before the Supreme Court followed suit, various other parts of the world had taken a narrow approach towards patent eligibility,⁹¹ thereby, enabling researchers to advance more quickly than American researchers. For instance, a French physicist found one mutation by using the BRCA DNA sequence before *Myriad*’s patent was held invalid,⁹² exemplifying that permitting restrictive use of naturally-occurring products keeps others from using the information contained in the products to come up with new and unique scientific principles.

While the *Myriad* Court merely reiterated what it already previously established: Patent protection will only be rewarded for human ingenuity and

85. See *Myriad Genetics*, 133 S. Ct. at 2109–10.

86. See *id.*

87. *Id.* at 2109.

88. *Mayo*, 132 S. Ct. at 1293.

89. See *Myriad Genetics*, 133 S. Ct. at 2109–10.

90. *Id.* at 2109.

91. See Andrews, *supra* note 9, at 86.

92. *Id.* at 90.

true innovations, the decision greatly impacts geneticists, health care professionals, and patients. No longer may a person economically benefit from an existing scientific principle by simply discovering the natural components of that principle. To analogize, an amateur cook cannot take a widely known recipe, mix up the necessary ingredients, and claim that no one else, not even the chef who originally came up with the recipe, can ever use that recipe or any other recipes that include those pre-existing ingredients because discovering all the ingredients was a tedious task. The law in *Myriad* is clear: mere discoveries of pre-existing natural products, no matter how difficult and cumbersome, are not “innovations” in the context of the Patent Act.

